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Application No.: 09/389,537  
Filed: September 2, 1999  
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### **REMARKS**

The present invention provides isolated enzymes comprising an amino acid sequence which is at least 70% identical to the amino acid sequence set forth in SEQ ID NOs: 25-32 when aligned using a sequence alignment program, for example, the BLASTN program of the National Center for Biotechnology Information. Other sequence alignment programs can also be used. Examples of the invention enzymes include those that are microbially derived and which have transaminase or aminotransferase activity.

Claims 17 and 18 were pending before this response. By the present communication, claims 17 and 18 are amended and new claims 19-27 are added to define Applicants' invention with greater particularity. These amendments add no new matter as the new claim language is fully supported by the specification and original claims. Accordingly, claims 17-27 are currently pending as shown in attached Exhibit A.

### **The Rejection Under 35 U.S.C. § 112, First Paragraph**

Applicants respectfully traverse the rejection of claim 17 under 35 U.S.C. § 112, First Paragraph, for allegedly lacking sufficient written description to enable those of skill in the art to make and use the invention without undue experimentation. Applicants disagree with the Examiner's assertion that the specification does not disclose identifying characteristics which would allow to distinguish a mere protein from any enzyme or specifically an aminotransferase or transaminase" (Office Action, pages 2-3). The invention isolated enzymes, as defined by amended claim 17, are required to comprise "an amino acid sequence which is at least 70% identical to the amino acid sequence set forth in SEQ ID NOs: 25-32 when aligned using the BLASTN program of the National Center for Biotechnology Information, wherein the enzyme has activity as a transaminase or aminotransferase."

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Applicants respectfully submit that the requirement of at least 70% amino acid identity to a known amino acid sequence is a *structural* characteristic. In addition, to make this structural determination regarding a putative enzyme, those of skill in the art may utilize the BLASTN program of the National Center for Biotechnology Information. At the filing of the present application, the BLASTN program of the National Center for Biotechnology Information was already a well known, publicly available (i.e., via the internet) computer program with built-in rules for aligning amino acid sequences and determining, among other things, the percent identity between any amino acid sequence, such as a putative enzyme sequence, and the amino acid sequences set forth in SEQ ID NOS 25-32. This aspect of the invention can be practiced sitting at a desk at home.

Claim 17 also requires that the putative enzyme meet a functional test (i.e. have activity as a transaminase or aminotransferase). Applicants respectfully submit that tests for determining whether a polypeptide has activity as a transaminase or aminotransferase were well known in the art at the filing of the present application, as can be determined by a review of the relevant technical texts available to those of skill in the art at the filing date of this application. In addition, the Specification discloses an assay that can be used to determine whether a polypeptide has activity as a transaminase.

Therefore, Applicants respectfully submit that those of skill in the art could make and use the invention, as defined in amended claim 17, without undue experimentation. Accordingly, reconsideration and withdrawal of the rejection of claim 17 as allegedly lacking an enabling disclosure are respectfully requested.

### **The Rejection for Double Patenting**

A. Applicants respectfully traverse the rejection of claim 18 under 35 U.S.C. § 101 for allegedly claiming the same invention as that of claim 16 of U. S. Patent No. 5,814,473. The invention method for transferring an amino group from an amino acid to an

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$\alpha$ -keto acid, as defined by amended claim 18, distinguishes over that of claim 16 of U. S. Patent No. 5,814,473 by requiring "contacting an amino acid in the presence of an  $\alpha$ -keto acid with an enzyme which is at least 70% identical to the amino acid sequence set forth in SEQ ID NOS: 25-32 when aligned using the BLASTN program of the National Center for Biotechnology Information and thereby transferring an amino group from the amino acid to the  $\alpha$ -keto acid. Therefore, present claim 18 is much broader in scope than that of claim 16 of U.S. Patent No. 5,814,473. Accordingly, Applicants respectfully submit that the two claims do not claim "the same invention" as would be required to support a rejection under 35 U.S.C. § 101. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

B. Applicants respectfully traverse the rejection of claim 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U. S. Patent No. 5,814,473. Submitted herewith is a Terminal Disclaimer disclaiming the terminal part of any patent granted on the above-identified Application No. 09/389,537 that would extend beyond the expiration date of U.S. Patent No. 5,814,473. Such Terminal Disclaimer shall be enforceable only for and during such period that the legal title to claims 15 and 16 of U. S. Patent No. 5,814,473 is the same as the legal title to the above application. In view of the Terminal Disclaimer submitted herewith, Applicants respectfully submit that present claims 17 and 18 are both unobvious under the judicially created doctrine of obviousness-type double patenting in view of claims 15 and 16, respectively, of U.S. Patent No. 5,814,473. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

In addition, Applicants respectfully traverse the provisional rejection of claims 17 and 18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/412,184. Submitted herewith is a Terminal Disclaimer disclaiming the terminal part of any patent granted on the above-identified Application No. 09/389,537 that would extend beyond the expiration date of any patent granted on Application No. 09/412,184. Such Terminal Disclaimer shall be enforceable only for and

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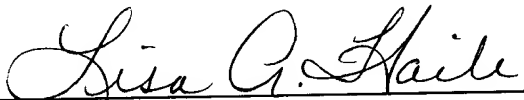
during such period that the legal title to any patent granted on Application No. 09/412,184 is the same as the legal title to the above application.

In view of the Terminal Disclaimers submitted herewith, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 17 and 18 for alleged double patenting over U.S. Patent No. 5,814,473 or any patent that may be granted on Application No. 09/412,184.

In view of the above amendments and remarks, reconsideration and favorable action on claims 17-27 are respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date: 4/24/01

  
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Attachment: Exhibit A

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## EXHIBIT A

### Version with Markings to Show Changes Made

17. (Amended) An isolated enzyme comprising a member selected from the group consisting of an enzyme comprising an amino acid sequence which is at least 70% identical to the amino acid sequence set forth in SEQ ID NOs: 25-32 when aligned using the BLASTN program of the National Center for Biotechnology Information, wherein the enzyme has activity as a transaminase or aminotransferase.

18. (Amended) A method for transferring an amino group from an amino acid to an  $\alpha$ -keto acid comprising:

contacting an amino acid in the presence of an  $\alpha$ -keto acid with an isolated enzyme selected from the group consisting of an enzyme which is at least 70% identical to the amino acid sequence set forth in SEQ ID NOs: 25-32.